



Food and Drug Administration
Rockville MD 20857

Office of Combination Products
15800 Crabbs Branch Way, Suite 200 (HFG-3)
Rockville, Maryland 20855

Dear Sponsor:

Combination products (i.e., drug-device, drug-biologic, and device-biologic products) are increasingly incorporating cutting edge, novel technologies that hold great promise for advancing patient care. Since combination products involve components that would normally be regulated under different types of regulatory authorities, and frequently by different FDA Centers, they also raise challenging regulatory, policy, and review management issues.

FDA's Office of Combination Products (OCP) serves as a focal point for combination product issues for sponsors developing these products, and works with FDA's Center for Biologics Evaluation and Research, Center for Devices and Radiological Health, and Center for Drug Evaluation and Research, to develop guidance to clarify the agency's regulation of combination products. The Office's duties include:

- assigning an FDA Center to have primary jurisdiction for review of a combination product;
- ensuring timely and effective premarket review of combination products by overseeing reviews involving more than one agency center;
- ensuring consistency and appropriateness of postmarket regulation of combination products; and
- resolving disputes regarding the timeliness of premarket review of combination products.

We are actively working on a number of policy areas that we hope ultimately will clarify the regulation of combination products, such as the definition of primary mode of action (criterion used to assign combination products to agency centers); determining the appropriate number of marketing applications for a combination product; and determining appropriate manufacturing/quality system provisions and adverse event reporting requirements for combination products. More information about our Office and the assignment, regulation and review of combination products is available on our website at <http://www.fda.gov/oc/combination/>, and the site is updated as new information becomes available.

OCP is available to you as a resource for questions or issues that may arise throughout the development of your combination product. You may reach us at the above address, by telephone at (301) 827-9229, or by email at combination@fda.gov. We look forward to working with you.

Sincerely yours,

A handwritten signature in black ink that reads "Mark D. Kramer".

Mark D. Kramer
Director
Office of Combination Products